DEPARTMENT OF VETERANS AFFAIRS
Office of Acquisition and Logistics
National Acquisition Center
P.O. Box 76
Hines, IL 60141

May 4, 2021

Dear Manufacturer,

This correspondence is to inform you that VA has clarified its guidance on New Product, New Package Size, and NDC number change designations. It also covers Penny Pricing for consecutive years, Methodology changes, Transfer Relief requests, Non-TAA drugs and Offsets on overcharges relevant to implementation of Public Law 102-585, Section 603 (38 U.S.C. § 8123) (Public Law).

PRICING OF DRUGS: New Products, New Package Sizes and NDC Number Changes

In October 2010, VA issued guidance on pricing new package sizes of existing covered drugs. Since this initial guidance, VA has received several inquiries regarding whether a particular NDC should be treated as a "new NDC" or a "new package size" (NPS). This updated guidance is intended to provide more information on how VA views this issue.

Although 38 U.S.C. 8126(h)(2) and the Master Agreement define "covered drug", in practice, VA's current interpretation is that legend products (products requiring a prescription) are "covered drugs" if:

1. FDA's Orange Book application number begins with a "NDA" and that "NDA" is "RLD" (Reference Listed Drug) "Yes" for at least one Active Ingredient (for the same number) or
2. FDA's Orange Book application number begins with a "BLA" for at least one Active ingredient.

VA has and intends to continue to entertain arguments to the contrary on a case-by-case basis. Please direct relevant communications to: AMMHIN.PL102585@va.gov.

PRODUCTS THAT WILL BE TREATED AS "NEW" COVERED DRUGS, RECEIVING AN INDEPENDENTLY COMPUTED FEDERAL CEILING PRICE (FCP)

1. New FDA approved products that have a New Drug Application (NDA), new drug application authorized generic (NDA-AG), or new Biologic License Application (BLA).

2. An “unbranded biologic” product with a new NDC approved under an existing BLA without the brand name (proprietary name) on its label. The product should not be different in strength, dosage form, route of administration or presentation.
3. Reformulated products which have been issued a new NDA or BLA.
4. Returning NDA products that have been off the market and have had no sales for more than 1 year, where none of the product remains in the pipeline and/or the last lot produced has expired.
5. “Authorized Generics” manufactured under the original NDA referred to as New Drug Application-Authorized Generic (NDA-AG), as long it has its own separate identity (unique trade name), marketing, and pricing (it must not be priced and/or marketed as if it were the same product as the “branded” covered drug).

PRODUCTS THAT WILL FOLLOW VA’S OCTOBER 2010 GUIDANCE ON PRICING NEW PACKAGE SIZES (NPS) OR CONTINUE THE ESTABLISHED FCP OF THE “ORIGINAL” PRODUCT

1. Simple NDC changes of a product to reflect changes in the product’s ownership or marketing responsibility.
2. NDC changes because the color, color coating, tablet size or other attribute of a product has changed (container, delivery system, etc.), except where the change is done under a new NDA.
3. New NDC with the same concentration of an existing NDC, but different total volume offered.
4. Addition of value-added products, such as creating a combination kit. However, the FCP may be increased using the original FCP plus the current price of the added-value product. For example, if adding an over-the-counter scrub to a skin ointment, the existing FCP could be increased by the reasonable cost of the added product (typically up to 10% as determined by the Public Law 102-585, Section 603 (38 U.S.C. § 8126) Policy Group (Policy Group).
5. Products that have been out of production and off the market for less than 12 months will be established by increasing the existing FCP by any public law season price increases based on CPI-U, if applicable.

NON-FAMP METHODOLOGY CHANGE REQUESTS – INCLUDING SMOOTHING

As a general matter, as stated in annual instruction letters from VA’s PBM, most recently October 10, 2020, any anticipated changes in a covered drug manufacturer’s methodology used to calculate non-FAMP data must be submitted to VA for review and approval. VA would like to reiterate that VA-approved non-FAMP methodology changes, including smoothing, are prospective only and cannot be applied retroactively back to prior years.

Additionally, although manufacturers may change from one methodology to another, the manufacturer must submit a new request for *each* change, even if the methodology was previously approved by VA and used in prior FCP years.

As a reminder, for each methodology change, the third quarter "non-FAMP Old" must also be restated with the "non-FAMP New" methodology to ensure an apples-to-apples comparison of the third quarters for the purposes of determining the additional discount in calculating FCPs.

Changes in non-FAMP methodology requests should be sent to AMMHIN.PL102585@va.gov.

APPLICATION OF TRANSFER RELIEF

When a covered drug transfers from one manufacturer to another, the transferee gets two types of relief: (1) no additional discount and (2) no dual calculation. For products transferring in the first through third quarters of the transfer year, the transfer relief is allowed in the first year after transfer. If the product transfers in the fourth quarter, transfer relief is allowed in the second year after transfer.

Requesting transfer relief is the manufacturer's responsibility. When a transfer occurs between the first through third quarters, manufacturers should request transfer relief during the annual public law season in the year the transfer took place. When a transfer occurs in the fourth quarter, manufacturers should request transfer relief during the public law season following the year of transfer. If the manufacturer fails to request transfer relief in a timely manner, it will not be granted retroactively.

PENNY PRICING IN SECOND CONSECUTIVE YEAR

The PBM's Annual Guidance Letter explains that if a covered drug had no reportable sales during the fiscal year, the FCP is the lower of the (1) prior year's FCP increased by the Consumer Price Index – Urban (CPI-U) **or** (2) FSS price in effect 9/30, increased by the CPI-U.

When no reportable sales continue in the subsequent year (a second year), the penny price would continue into the next year, regardless of whether the company maintains a single or dual pricelist. However, the Policy Group does not believe that second-year penny pricing is the intent of the statute. Therefore, in response to manufacturer concerns, the following guidance is provided:

> If the Non-FAMP calculation results in a penny for a second year, the FCP will be calculated by starting with the last calculated FCP that was not a penny price and applying the CPI-U increase to the FCP for each year it was a penny until the current year:

Example:

- 2019 FCP calculated according to PL and VA guidelines was 25.48
- 2020 FCP was a penny
- 2021 FCP also calculates to a penny.
- 25.48 * 1.71% (2020 CPI-U) * 1.37% (2021 CPI-U) = 26.27 will be used for the 2021 FCP

NO OFFSETS ON OVERCHARGES

It has been a long standing policy that, in general, no offsets are permitted when determining the amount of overcharges owed to the Government for **manufacturer** computing errors in calculating non-FAMPs and FCPs not in accordance with the Public Law and related VA guidance. VA's guidance is consistent with the following concerns:

- The Public Law establishes the maximum price that can be charged, not a minimum (often pricing is below the ceiling price).
- Non-FAMP calculations are the sole responsibility of the manufacturer.
- While retroactively adjusting pricing because of overcharges is consistent with the statutory scheme, adjusting pricing because of undercharges is not and is problematic because such price changes may have impacted VA's purchasing (and contracting) decisions.

Non-TAA status reminder:

- Covered drugs with a non-TAA status, must continue to report Non-FAMP data annually.
- All covered drugs NDCs should be offered for procurement on the Federal Supply Schedule (FSS), regardless of TAA status.

If you have any questions about any of the above information, please contact The Public Law Policy Group at AMMHIN.PL102585@va.gov

Sincerely,

DIANA D. LAWAL 265225

Digitally signed by DIANA D. LAWAL 265225
Date: 2021.05.04 15:21:27 -05'00'

Diana D. Lawal
Chair, Public Law Policy Group